JUN 11 2001 K004017

510(k) Summary

Submitter:

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Mortara Instrument, Inc.
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Contact: Harlan Van Matre (see above)

Trade Name: H-Scribe
Common Name: Holter Analysis System
Classification Name: Programmable Diagnostic Computer
(Per 21 CFR 870.1425)

Legally marketed devices to which S.E. is claimed
Cardiodata MK5 Holter Analysis System – 510(k) K900607
Zymed Holter Scanner, Model 2010 Plus – 510(k) K 955015

Description:

The H-Scribe Holter Analysis system is a PC based diagnostic tool consisting of a Holter analysis software application running on a commercial PC using Windows 98 operating system. Designed in conjunction with the Mortara H-12 Holter recorder, the H-Scribe analyzes prerecorded patient's ECG data that has been stored by the H-12 recorder, or other compatible tape or digital recorders. The system provides three channels of full disclosure for arrhythmia analysis and 12-lead ST segment analysis. The software automatically detects arrhythmia and ST events, and creates summary tables, trends and a final report regarding a variety of cardiac data indices. The cardiac data provided by H-Scribe is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

System features and options include a DVD RAM drive provided for long term archival of full disclosure recordings on DVD disks, an included modem for remote technical support, a network card for remote printing and data transfer, and networking capability allowing interface to Hospital Information Systems, through standard protocols.

Intended use:

The H-Scribe Holter system is intended to acquire, automatically analyze, edit, review, report and store prerecorded ECG data of patients that have been connected to the Mortara H-12 digital recorder or to other compatible tape or digital recorders. The cardiac data and analysis provided by H-Scribe Holter system is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various cardiac rhythm patterns.

Indications for use:

The H-Scribe Holter system is intended for use in a clinical setting, by qualified medical professionals, for patients requiring ambulatory (Holter) monitoring of 24 – 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. The analysis software package includes, among others, detection and reporting features appropriate to the indications below:

- Evaluation of adult patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia.
- Evaluation of adult patients for ST segment changes
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Infant patient evaluation is limited to QRS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2001

Mr. Harlan Van Matre
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224

Re: K004017
Trade Name: Mortara H-Scribe Holter Analysis System
Regulation Number: 870.2800
Regulatory Class: II (two)
Product Code: 74 MLO
Dated: March 6, 2001
Received: March 7, 2001

Dear Mr. Van Matre:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K004017

Device Name: **Mortara H-Scribe Holter Analysis System**

The H-Scribe Holter system is intended to acquire, automatically analyze, edit, review, report and store prerecorded ECG data of patients that have been connected to the Mortara H-12 digital recorder or to other compatible tape or digital recorders. The cardiac data and analysis provided by H-Scribe Holter system is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various cardiac rhythm patterns.

The H-Scribe Holter system is indicated for use in a clinical setting, by qualified medical professionals only, for patients requiring ambulatory (Holter) monitoring of 24 – 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. The analysis software package includes, among others, detection and reporting features appropriate to the indications below:

- Evaluation of adult patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia
- Evaluation of adult patients for ST segment changes
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of infant patients limited to QRS detection only

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21CFR801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004017